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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,962	12/29/2000	David E. Catcheside	10552.13USC1	2958

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/04/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/751,962

Applicant(s)

CATCHESIDE, DAVID E.

Examiner

David A Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in Paper No. 8 is acknowledged.

Claims 70-127 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Claims 1-69 are ready for examination in the instant application.

Priority

Applicant's claim for domestic priority to U.S. Application No. 08/977,171 under 35 U.S.C. 120 is acknowledged.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on March 2, 2002 (Paper No. 3) has been considered by the examiner, and a copy is attached to this Office Action.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
it appears as if the declaration was signed in 1978. This clearly cannot be correct.

Appropriate correction is required.

Specification

The disclosure is objected to because of the following informalities: in the Brief Description of the Drawings, there is no reference to the sub-panels of the figures. Specifically, Figure 1 and 2 have multiple panels (A, B and C [figure 2 only]), but there is no reference to these panels in the first line of the Brief Description of the Drawings for each drawing.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 8-36 and 42-69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a haploid or a diploid fungal cell comprising a recombinant genome comprising a heterologous DNA functionally coupled to *any* recombinational hotspot. The claims read on a broad genus of recombinational hotspots.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between

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function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims a "recombinational hotspot" by function only, without any disclosed or known correlation between the elements and their function. The specification only provides teachings regarding the use of "recombinational hotspots" such as *cog*, which is known in the art. The specification does not teach how to identify additional "recombinational hotspots" that can be used in the invention, either by showing what characteristics are required by describing what elements of a sequence makes it useful as a "recombinational hotspot" or by describing a method of identifying "recombinational hotspots". The skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification because the specification only discloses the use of those hotspots that have been already described in the art, specifically *cog*.

The prior art does not provide sufficient information on the subject to overcome the written description requirements. There is no description in the prior art that allows one to envision a representative number of "recombinational hotspots" by disclosing structural or functional features of these hotspots so that one of skill in the art could identify and use said sequences in the instant invention. It is unclear from the prior art how to identify "recombinational hotspots" because it is unclear what actually makes a particular sequence a "recombinational hotspot". Thus the skilled artisan cannot rely on the prior art to envision a

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sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

Neither the specification of the instant application or the prior art teaches a structure-function relationship for a representative number of "recombinational hotspots". As a result, the skilled artisan would not be able to envision the claimed invention by relying on the teachings of the prior art or the instant specification. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-67 of U.S. Patent No. 6,232,112 (henceforth the '112 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application represent a genus of claims that are anticipated by the species claims of the '112 patent. Claims 1 and 34 of the instant application

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are identical to claims 1 and 33 of the '112 patent with the exception that the instant claims do not recite the limitation of "the recombination hot spot being *Neurospora crassa cog*, 3' - of *his-3* and 3' of *am* in *Neurospora crassa*, 3' of *his4* and 3' of *arg4* in *S. cerevisiae*, or within *ade6* in *S. pombe*". The instant claims read on any recombinational hotspot, whereas the claims of the '112 patent read on the specific recombinational hotspot *cog* in *Neurospora crassa*, placed in specific regions of the genomes of *N. crassa*, *S. cerevisiae* and *S. pombe*. Therefore, claims 1 and 33 of the '112 patent, being a specific embodiment of the instant claims, anticipate the claims 1 and 34 of the instant application.

The limitations that are recited by the depending claims of the instant application (claims 2-33 and 35-69) are all present in the depending claims of the '112 patent (claims 2-32 and 34-67). Since the limitations were applicable to the specific claims of the '112 patent, they are equally applicable to the genus claims of the instant application. Therefore, it would have been obvious to apply the limitations to the broad claims because they are applicable to the specific claims that are contained within the scope of the broad claims.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the '112 patent. Also, if both patents are issued and the patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the '112 patent, then two different assignees would hold a patent to the same claimed invention and thus improperly there would be possible harassment by multiple assignees.

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Allowable Subject Matter

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
December 2, 2002

Gerald D. Lipp
PATENT EXAMINER
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